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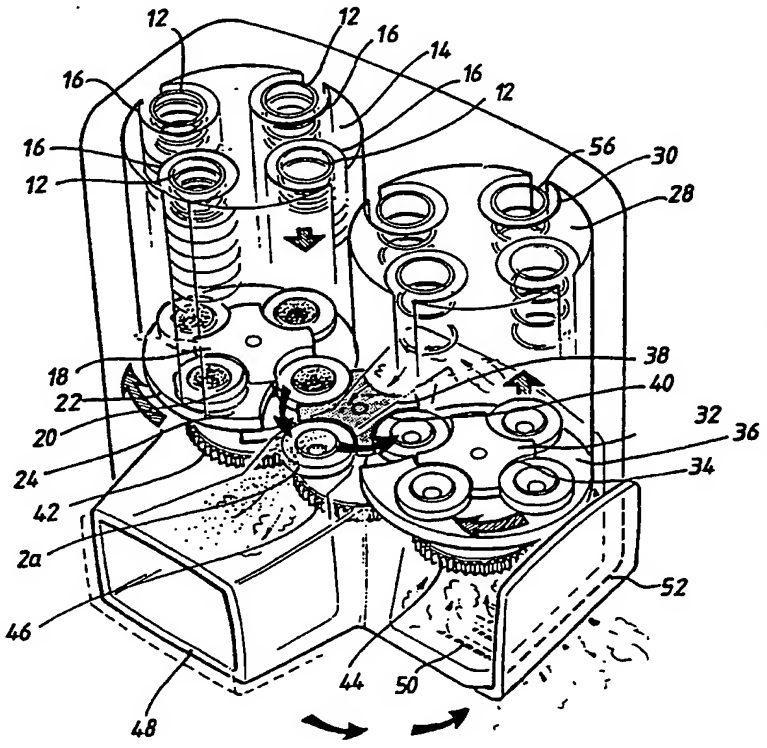
(57) Abstract

An inhalation device is provided by means of which material in powder form can be inhaled. A stack of powder containers (2) is held in the device and is urged towards one end by a spring (12) or other resilient member. A use station is located at or adjacent that end, where powder can be inhaled from a container (2a) at the use station. Used containers (2) are fed to a storage area, for example a second stack which may be interconnected at its lower end, via the resilient member, with the lower end of the first stack.



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INHALATION DEVICE

This invention relates to an inhalation device for use in the inhalation of material in powder form. More particularly, it relates to a device by means of which medicament in powder form can be inhaled, and it is so described below.

According to the present invention there is provided an inhalation device by means of which material in powder form can be inhaled, comprising means for holding a stack of powder containers, means for feeding the containers individually to a use station, and means for enabling the powder to be inhaled from a container at the use station.

The invention further provides an inhalation device by means of which material in powder form can be inhaled, comprising means for holding a stack of powder containers, means for resiliently urging the stack in a direction from a first end thereof to a second end thereof, a use station at or operatively connected to the said second end, and means for enabling powder to be inhaled from a container at the use station.

The invention also provides an inhalation device by means of which material in powder form can be inhaled, comprising means holding a stack of powder containers each of which has a powder-containing depression therein, means for feeding each of the containers to a use station, and inhalation means for enabling the powder to be inhaled from a container at a use station, said inhalation means comprising wall means which cooperate with the said depression to define a venturi.

The invention additionally provides an inhalation device by means of which material in powder form can be inhaled, comprising means for holding said material therein, means for actuating the device to permit

inhalation, and a safety catch which in an operative position prevents actuation of the device and which in an inoperative position permits operation of the device.

In another aspect of the invention there is provided a cartridge for use in an inhalation device, comprising means containing a first stack of unused powder containers, means for receiving at a first end used containers from a first end of the first stack, to form a second stack, and a force-applying means, one end of the force-applying means applying a substantially constant force to a second end of the first stack and the other end of the force-applying means applying a substantially constant force to a second end of the second stack.

The invention is further described below with reference to the accompanying drawings, in which:

Figure 1 is an isometric view of a first embodiment of the invention;

Figures 2a and 2b show details of the embodiment of Figure 1, namely part of a stack of powder containers and a helical ramp;

Figure 3 is an isometric view of a second embodiment of the invention;

Figures 4a and 4b show, in diagrammatic form, and by way of example, two air flow patterns which may be generated to empty the powder from the containers;

Figure 5 is a side view, partly in section, showing diagrammatically another embodiment of the present invention;

Figure 6 is an underplan view of the upper portion of the embodiment shown in Figure 5, on a larger scale;

Figure 7 is a section on line III-III in Figure 6, but showing only one of the components shown in Figure 6;

Figure 8 is a perspective view of a device embodying the principles of Figures 5 to 7;

Figure 8a is a view from above showing part of

the device of Figure 8;

Figure 8b is a vertical section through part of the device of Figure 8, showing in more detail the design of the mouthpiece thereof;

Figure 9 shows a single powder container;

Figures 10a and 10b show part of an embodiment employing a rotary slider, with Figure 10a being a section on line X-X in Figure 10b; and

Figures 11a and 11b, and 12a and 12b are views corresponding to Figures 10a and 10b, with the components in other positions;

Figure 13 is a longitudinal section, with portions cut away, showing a further embodiment;

Figure 13a shows a detail of the embodiment of Figure 13;

Figures 14a and 14b show, diagrammatically and in section, the upper portion of the embodiment of Figures 13 and 13a in its inoperative and operative positions, respectively; and

Figure 15 is a section through the portion shown in Figure 14b, taken at right angles thereto.

The embodiment illustrated in Figures 1, 2a and 2b uses powder containers in the form of shallow cups 2. Other forms of powder container may be used instead, and some of these are described below. Each cup 2 has a shallow depression 4 in its upper surface, the depression 4 being circular in plan view and smoothly curved in vertical section. The depression terminates at its upper end in an annular bead 6 which acts as a sealing ring to provide a seal between each cup and the cup above it, thereby sealing the volume within the depression. A pre-metered quantity of medicament 8 is provided in each depression. In Figure 2 the medicament is shown as occupying only part of the volume of the depression, but it could be such as to occupy the whole volume. The depression in the topmost cup is closed by a solid disk 10, and a compression spring 12 bears on the upper surface of

the disk 10. Figure 2a shows three cups, but it is to be understood that in practice a much larger number of cups would normally be stacked one above the other.

Figure 1 shows an inhalation device which comprises a feed magazine 14 having four cylindrical bores 16 which are spaced at 90° from one another round the circumference of the magazine. Each bore 16 contains a stack of cups 2, each with a respective disk 10 and spring 12 at its upper end.

The feed magazine 14 is rotatable about its longitudinal axis, and carries at its lower end a starwheel 18. The starwheel 18 has four arcuate cut-outs 20 which receive, respectively, the lowest cup of a given stack. Immediately below the starwheel 18 is a non-rotating disk 22 having an upper surface 24 in the form of a ramp. The amount by which the ramp descends over a complete turn, as represented by the step 26, is equal to the vertical height of a single cup.

The device further comprises a collection magazine 28 having four bores 30 arranged therein in a similar manner to the way in which the bores 16 are arranged in the feed magazine 14. The collection magazine 28 is rotatable about its longitudinal axis, and carries, at its lower end, a starwheel 32 having four arcuate cut-outs 34. A non-rotating disk 36 is located beneath the starwheel 32, the disk 36 being the mirror image of the disk 22.

Located between the starwheels 18 and 32, and coplanar therewith, is an indexing starwheel 38. This also has four arcuate cut-outs, denoted as 40. The cut-outs in the three starwheels are so arranged that, as can be seen in Figure 1, a cup can be engaged between the starwheels 18 and 38 or between the starwheels 32 and 38. The necessary alignment between the starwheels can be achieved by providing gear wheels 42, 44 and 46 on the underside of the starwheels, the gear wheels meshing with one another. However, if the cups are sufficiently rigid the gear wheels

may be dispensed with, since the cups themselves, when engaged between adjacent starwheels, can provide the necessary alignment.

Figure 1 further shows a mouthpiece 48 through which the user can inhale. This assumes that the device is to be used for oral inhalation. If it is to be used for nasal inhalation a nasal adapter will replace the mouthpiece 48. The device is provided with an air inlet 50, shown by way of example in the form of a grille. A lever 52 is pivotally mounted on the underside of the device for movement through 90° between an inoperative position and an operative position (shown). In the inoperative position the lever covers the mouthpiece and covers the air inlet 50. It uncovers both of these in the operative position.

The manner in which the device operates is as follows. When the user desires to inhale medicament, the user moves the lever 52 from the inoperative position to the operative position. The lever is connected by suitable means, which include a ratchet mechanism, (not shown) to one or other of the magazines via its respective starwheel or gear wheel (if provided) or to the indexing starwheel 38. In any of these events movement of the lever through 90° from the inoperative position to the operation position not only uncovers the mouthpiece and air inlet but also moves all three starwheels through 90°. This brings a powder-containing cup 2 from one of the stacks into a use station which is shown as being occupied by the cup denoted 2a in Figure 1. The device is provided with suitable air flow guide means (not shown) so that when the user then inhales, air is caused to flow in through the air inlet 50, through the depression 4 in the cup, and out through the mouthpiece 48 carrying the powder with it. A suitable air flow guide means may comprise a venturi, with the throat of the venturi being located adjacent the depression 4. When the lever 52 is returned to the inoperative position the ratchet mechanism ensures that this has no effect on the

magazines.

Figures 4a and 4b show two forms of air flow which may be established with a view to emptying the powder from the depression 4. Figure 4a shows a laminar flow, and Figure 4b shows a turbulent flow induced by a sharp edge 54.

The above described rotation of the lever through 90° from the inoperative position to the operative position also causes the empty cup (if any) at the use station to be moved to the bottom of one of the stacks in the collection magazine 28. Each stack in the collection magazine may be lightly compressed by a spring 56, or any other suitable means, to prevent the empty cups rattling in the magazine 28. The springs 12 in the feed magazine 14 serve a similar purpose, but in general need to be stronger than the springs 56, since they must ensure that the cups at the bottom of the stacks in the feed magazine successively engage in the space defined between the starwheels 18 and 38.

The ramp 24 ensures that the stacks of cups in the bores 16 are progressively lowered as the magazine 14 rotates. Thus, when a cup reaches the position in which it is engaged between the starwheels 18 and 38 it can then be carried to the use station without being impeded by the downward force of the caps above it in the stack. This is because the lower surface of the lowest of those other caps engages the upper surface of the ramp 24 at the upper end of the ramp immediately that movement to the use station commences.

Figure 3 shows an alternative embodiment. This comprises a feed magazine 114, similar in function to the magazine 14 of Figure 1, and having a starwheel 118. An indexing starwheel 138, similar in function to the starwheel 38 of Figure 1, brings a cup from which powder is to be dispensed to a use station, where the cup is denoted by reference 2a. The user inhales through a mouthpiece 148, which is covered when not in use by a dust cover 149,

and air enters the device through an air inlet 150. In place of the lever 52, the feed magazine is indexed through successive steps of 90° by an indexing wheel 152. The wheel 152 is connected to the magazine 114 via a ratchet mechanism (not shown) to ensure that the magazine can only be turned in the correct direction. In place of the collection magazine 28 used in Figure 1, the device of Figure 3 has a storage chamber 128. This is provided internally with a helical ramp down which empty cups travel as they are pushed by the cups behind them. Adjacent turns of the ramp are spaced from one another by a distance such that the cups have a slight friction fit in the ramp and are therefore prevented from rattling.

As mentioned above, other forms of powder container may be used in place of the illustrated cups. One simple way of forming a stack of containers is with a stack of washers placed one on top of another. The cylindrical aperture defined by the stack of washers is filled with powder, and the movement of a washer to the use station carries with it an amount of powder equal in thickness to the thickness of the washer itself.

Another possibility is to use cups which are each hermetically sealed, for example, by a foil lid, and which do not rely on being sealed by the cup or disk immediately above them. In that case some means for removing or opening the hermetic seal is required at the use station.

Depending on the volume of the containers used, and depending on the nature of the medicament, the device of the invention may be used to dispense an active ingredient either with or without a carrier.

Although the embodiments thus far described are advantageous in a number of respects, they do suffer from one potential difficulty. The powder containers are taken from a separate stack of unused containers and, after the powder has been inhaled therefrom, are transferred to a separate stack of used containers (in the case of Figure 1) or a storage chamber in the case of Figure 3). The stacks

are kept in a state of compression. In the case of the stack of unused containers this is for two reasons. Firstly, it assists in feeding the powder containers in turn to the use station. Secondly, in the preferred embodiments the containers are open-topped, each container being closed by the container above it, and so the containers need to be pressed together to prevent powder escaping and to prevent the ingress of moisture and contaminants. In the case of the stack of unused containers in Figure 1, they are kept under compression to avoid them rattling, an effect which might be disconcerting to a user. However, keeping the stacks in a state of compression presents a difficulty, since during operation the stack of unused containers, where present, progressively decreases in size and the stack of used containers progressively increases in size. This results in the compression on the unused stack decreasing during operation and the pressure on the used stack increasing during operation. Neither effect is desirable.

In order to substantially overcome this difficulty there is provided, according to an aspect of the invention, an inhalation device by means of which material in powder form can be inhaled, comprising means for holding a first stack of unused powder containers, means for holding a second stack of used powder containers, means for feeding each of the containers from a first end of the first stack to the use station and thence to a first end of the second stack, means for enabling the powder to be inhaled from a container at the use station, and a force-applying means, one end of the force-applying means applying a substantially constant force to a second end of the first stack and the other end of the force-applying means applying a substantially constant force to a second end of the second stack.

The embodiment is shown in Figures 5 to 9 a body 201 within which is formed a generally U-shaped passage 202. This passage comprises a first straight portion 203

which contains a stack 204 of unused powder containers 205, and a second straight portion 206 which contains a stack 207 of used powder containers. At the lower end of the stack 204 is a piston 208, and at the lower end of the stack 207 is a piston 209. A coil spring 210 is located, in a state of compression, within the U-shaped passage 201, with one end of the spring bearing against the piston 208 and the other end of the spring bearing against the piston 209. The spring 210 has end portions 210a and 210b in which adjacent turns of the spring are spaced somewhat from one another, whilst over the rest of the length of the spring the coils are located tightly against one another. The effect of this is that the spring 210 provides a flexible member of substantially constant length, with a substantially constant spring force being generated only by the end portions 210a and 210b.

It should be mentioned at this point that the form of spring just described is not essential for the operation of the present invention. Thus, for example, a simple compression spring, with the turns spaced apart over its whole length, could be used, However, to achieve the same compression stiffness as the spring 210 described, this would need to be made of relatively thick wire, and would therefore be less able to bend in the curved portion of the U-shaped passage. Another possibility is to use a flexible flat strip of metal or a plastics material, with a short compression spring at each end thereof. This has the advantage that the flat strip can be made highly flexible, and can therefore bend round a tighter radius than a conventional circular cross-section spring. However, it has the disadvantages that it involves additional components, and, in the case of a plastics strip, the material may creep with time. Yet another possibility is to use a flat strip formed into integral 'Z' springs at each end. This provides a highly flexible spring, whilst avoiding the need for more than one component, although the spring needs to be carefully

designed to achieve an adequate load. Metal is preferred as a material for the strip, since a plastics strip would be liable to creep.

A cover 211 is secured to the top of the body 201, and has a recess 212, which is rectangular both in vertical section and plan view on the underside thereof. A slider 213 is slidably mounted in the recess 212. The cover 211 has an air inlet passage 214 and an outlet passage 215 for air and powder. In practice, the passage 215 is connected to a mouthpiece or nosepiece for inhalation, though this is not shown in Figure 5. The slider 213 has a passage 216 which opens into the lower face of the slider 213. When the slider is in its left hand position (it is shown in an intermediate position in Figure 5) the opening in the passage communicates with the upper end of the stack 204 and the ends of the passage 216 communicate respectively with the passages 214 and 215. Thus, when the slider is in the left hand position, inhalation by the user through the mouthpiece or nosepiece attached to passage 215 causes air to flow in through passage 214 and thence through passage 216, entraining powder from the topmost of the containers 205 in the stack 204, and thence, with the powder entrained therein, out through the passage 215. Each of the containers 205 has a depression in its upper surface to hold the powder, and the shape of this depression is preferably such that it forms a smooth continuation with the adjacent wall of the passage 216, thereby to improve the efficiency with which powder is scoured from the depression by the air flow. The combination of the passages 214, 215 and 216, and the depression in the container 205, preferably forms a venturi.

The slider 213 operates to transfer each powder container, as it is used, from the top of stack 204 to the top of stack 207. The slider can be seen in more detail in Figures 6 and 7. It will be seen there that it has a recess 217 on the underside thereof, the recess being

defined by a shoulder 218 at one end and a ramp 219 at the other end. As the slider 213 moves from left to right, (as viewed in all of Figures 5 to 7), the shoulder 218 engages the left hand edge of the container 205 which is at the top of the stack 204. The slider moves this container onto the top of the existing stack 207 of used containers. The leading lower edge portion 220 of the slider 213 stays in contact with the top of the existing stack 207 until after the leading edge of the new used container 205 is over the edge of the stack 207. This ensures that the new used container is free to assume its desired position on the top of the existing stack.

When the slider 213 is then moved leftwards, the stack 207 is progressively compressed as the right hand edge of the top container in the stack is engaged by the ramp 219, until the leading edge portion 220 is over the top of the stack 207. During this leftward motion of the slider 213 the top container in the stack 207 is prevented from moving leftwardly by a non-return catch which is provided by a pair of pins 221. The pins pass through apertures 223 in the cover 211 and are biased towards one another, and in Figure 6 this is shown as being achieved by flexible resilient members 222. However, any suitable alternative biasing means could be used instead. The inner ends of the pins 221 are bevelled so that although they prevent the slider carrying containers from right to left they do not prevent the slider carrying containers from left to right.

One of the containers, with its depression 205a, is shown on a larger scale in Figure 9, and it can be seen to be generally rectangular in plan, but with two opposite bevelled edges. It will be appreciated that these are convenient from the point of view of the operation of the non-return catch in Figure 6.

The slider 213 may be moved back and forth, for example, by a lever 224, part of which is indicated in broken lines in Figure 7. The lever is pivotally mounted

on the body 201 by a shaft 225, which passes through a bore 226 indicated in Figure 5. The lever itself is not shown in Figure 5. The lever has an arcuate slot 227 which receives the end of a pin 228 which is fixedly secured in the slider 213. The lever 224 is shown moving clockwise, so as to carry the pin 228, and hence the slider 213, rightwardly.

The use of a pin and slot provides lost motion between the lever 224 and the slider 213. In an actual inhalation device this lost motion can be used as movement in which a cap closing the device is moved from a closed to an open position. Thus, in practice, the lever 224 could be constituted by the cap itself, with the initial part of the cap opening movement having no effect on the slider 213, and the final part of the cap opening movement serving to bring the last used container 205 from the stack 204 to the stack 207, and thus expose a fresh container at the top of stack 204 for use. An example of this is shown in Figures 8, 8a and 8b. This comprises a body 231 with a U-shaped passage 232, a compression spring 232 and a slider 233. The device is closed by a pivotally mounted mouthpiece cap 234 which provides the lever to move the slider apart against the resilient force of the spring. The cap 234 is pivotally mounted on the body 231 by shafts 237, and has arcuate slots 238 in which pins 239 engage, the pins 239 being attached to the slider.

The device has a mouthpiece 235. The mouthpiece 235 is hollow and has within it a venturi passage 240. The passage 240 has an air inlet 241 which air reaches preferably via an aperture 242 in the mouthpiece. The aperture 242 is sealed when the cap 234 is in its closed position, as illustrated. The slider 213 and a container 205 define together part of the wall of the venturi passage.

The principle of operation of the slider is substantially the same as in Figures 5 to 7, except that the pins 221 and resilient members 222 are replaced by a

single U-shaped spring 236. As shown in Figure 8a, the containers 205 are modified in that they are provided with cutouts 205b, and the ends of spring 236 engage in the cutouts of the used containers in stack 207. As each container moves from stack 204 to stack 207, it forces the ends of spring 236.

The embodiments shown in Figures 5 to 7 and Figure 8 employ a linearly moving slider. In an alternative embodiment the slider is moved arcuately by a pivotally mounted member, and this is shown in Figures 10a, 10b, 11a, 11b, 12a and 12b.

In the embodiment of Figures 10 to 12, the "slider" is constituted by a portion of the mouthpiece adjacent the body within which the stacks of powder containers are held. In these figures the body is denoted by reference 250, the mouthpiece by reference 251, the stack of unused containers by reference 252 and the stack of used containers by reference 253.

The mouthpiece 251 and body 250 are rotatable relative to one another through an angle of 90° about an axis which is the longitudinal axis of the device, i.e. an axis which is perpendicular to the plane of the paper in Figures 10b, 11b and 12b. The description will be given on the basis that the body is fixed and the mouthpiece rotates, but it will be understood that all that matters is the relative rotation between these two components. Rotation is limited to 90° by means of a stud 259 which is formed on the upper surface of the body 250 and which runs in an arcuate track 260 formed in the lower portion of the mouthpiece 251. This 90° rotation correlates with the fact that the stack 252 and the stack 253 are disposed at 90° with respect to one another about the axis of rotation of the mouthpiece. It must be understood, however, that the stacks could be at other angles with respect to one another, in which case the angle of rotation would be correspondingly different.

In the position shown in Figures 10a and 10b, the

container at the top of the full stack 252 sits in a cutout 254 on the underside of the mouthpiece. This cannot be seen in Figures 10a and 10b, but is visible in Figure 11a. The cup at the top of the empty stack 253 is held down by a portion of an inclined ramp 255, also formed on the lower portion of the mouthpiece 251. The cup at the top of the empty stack 253 is held in line with the rest of the stack by a resilient non-return catch 256 formed on the top of the body 250.

To index the device into a position in which it can be used, the mouthpiece 251 is rotated anticlockwise with respect to the body 250, as viewed in Figures 10b, 11b and 12b. This is indicated by arrows in each of the Figures 11b and 12b. At the start of this indexing process, the container at the top of the stack 252 is an empty container, this being the container from which the user last inhaled. As indicated in Figures 11a and 11b, this container, denoted there by reference 257, starts to move over the top of the stack 253 of empty containers, holding what was previously the top container of the stack 253 down while the ramp 255 moves away from the stack 253.

When transfer of the container 257 is complete, the catch 256 rises behind that container, as shown in Figure 12b. The venturi 258 in the mouthpiece is now in position over a full container at the top of the stack 252, and the device is in its primed position, ready for inhalation.

After the user has inhaled the powder from the top container, the mouthpiece is rotated clockwise through 90° to bring the device back to the position shown in Figures 10a and 10b. During this clockwise rotation the transferred container 257 is forced down into the stack 253 of empty containers by the ramp 255, and the catch 256 prevents the container 257 being drawn back towards the stack 252. When the 90° clockwise rotation has been completed, the newly emptied container on top of stack 252 snaps up into the cutout 254 in the mouthpiece 251, ready

for the next operation.

Figures 13 and 13a show a further embodiment in which, like the embodiments of Figures 5 to 12, there is a U-shaped passage containing a stack of unused containers and a stack of used containers. As in the case of the embodiments of Figures 5 to 8, containers are shifted from the top of one stack to the top of the other stack by a translational movement.

The device comprises a body 300 in which there is an outlet spout in the form of a mouthpiece 302. It would alternatively be possible for the device to be adapted for nasal use instead of oral use, in which case a nasal outlet would replace the mouthpiece. The same is true of the other embodiments described herein. The outlet end of the mouthpiece is closed by a cap 304 which is pivotally mounted on the body by means of a pivot 306 for pivotal movement with respect thereto. The powder containers are held in two stacks within a cartridge 307. Initially, all the containers are in a stack 308, which consists of a number of unused (i.e. full) containers surmounted by one empty container which acts as an initial lid to close off the top of the stack. The "top" for this purpose is the end of the stack nearer the mouthpiece 302. A stack of used (i.e empty) containers is formed during operation of the device in the chamber indicated by reference numeral 310. A window 311 is provided in the body 300, through which the stack of empty containers can be viewed when there are sufficient containers therein to fill the chamber 310 almost completely. This gives warning to the user when the full containers have almost all been used.

The end of the stack 308 remote from the mouthpiece 302 is seated on a spring member 312 which comprises a top member 314, a base member 316 and a compression spring 318 which urges the members 314 and 316 away from one another. One end of a U-shaped pusher member 320 bears against the base member 316. The pusher member 320 passes round a guide surface 322, over which it can

slide, and the other end thereof bears against a pad 324 which can be seen in Figure 13a and which is slidable in the chamber 310. The pusher 322 is in the form of a flexible plate, for example of a plastics material. The guide surface 322 is formed on one end of a rod 326, the other end of which, as can be seen in Figure 13a, provides a surface against which one end of a compression spring 328 can bear. The other end of the spring 328 bears against the end of a blade 330, the purpose of which is described below.

The shaft 306, which provides pivotal movement between the cap 304 and the body 300, carries a crank arm 332. Preferably, there is a pair of crank arms, one at each end of the shaft 306, only one of these arms being visible in Figure 13. The crank arm 302 and shaft 306 rotate with the cap 304, and thus with respect to the body 300.

Beneath the inner end of the mouthpiece 302, which is defined by a plate 334, there is mounted a slider 336 which is movable transversely with respect to the longitudinal axis of the mouthpiece 302, i.e. in a direction which is upward and downward as viewed in Figure 13. The slider has a lug 338 which is engaged by the end of the crank arm 332 after the arm has rotated clockwise from its illustrated position through an angle of about 45°. If a second crank arm 332 is provided there is a corresponding second lug 338 for it to engage. The slider also defines a bearing surface 340 with which a curved surface on the crank arm 332 can engage. The purpose of this is described below in connection with the operation of the device. It can further be seen in Figure 13 that the slider has a bead 342 on one end thereof. The end of a safety catch 344 operable by a button 346 engages behind the bead 342, and is urged into the engaging position by a compression spring 348. So long as the catch 344 engages behind the bead 342 the slider 336 cannot move.

As already mentioned, at the start there is a

complete stack 308 consisting entirely of unused containers except for that nearest the mouthpiece. The chamber 318 is empty. To use the device the user exerts a force on the button 346 to urge the catch out of engagement behind the bead 342, against the force of the spring 348. While still holding the button in that position the user pivots the cap 304 to uncover the mouthpiece 302. The first 45° of this pivotal movement has no effect on the operation of the device, thus allowing for example the sort of movement which might be made by someone, particularly a child, playing with it, without actually moving the slider. Further angular movement beyond the initial 45° causes the crank arm 332 to engage the lug 338 and, provided the pawl 344 is still out of engagement with the bead 342, the slider 336 is caused to move laterally. The resistance of the device to accidental operation is enhanced by the fact that lateral movement cannot take place, however, unless the user is at that point in time holding down the button 346.

At the start of this movement the empty container at the top of the stack 308 is in a recess 350 on the underside of the slider. The lateral movement of the slider transfers the empty container at the top of the stack 308 past the blade 330, which is depressed against the force of the spring 328, so that the empty container is on the end of the pad 324. The pad is thereby depressed, and movement of the pad is transmitted by the pusher 320 to the spring member 312. At this point the spring top 314 cannot move any further, so the result is that the compression spring 316 is compressed by an amount equal to the thickness of one container. The empty container which is now bearing against the pad 324 forms the start of the stack of used containers.

The above described movement of the empty container brings a full container into alignment with an opening 352 in the underside of the slider. A pair of passages 354, 356 with which the opening 352 communicates

are in alignment respectively with an aperture which communicates with the interior of the mouthpiece 302 and an aperture 358 in the plate 334 through which air can enter from the exterior of the device. Accordingly, when the user now inhales through the mouthpiece, air flows in through the aperture 358 and passage 356, entrains powder from the container, and flows out through the passage 354 into the mouthpiece and thence to the patient.

When the cap 304 is rotated back to its closed position, the curved surface on the rear of the crank arm 332 engages the surface 340 on the slider 336, and forces the slider back to its original position. During this movement the blade 330 prevents the empty container from moving back to the top of the stack 308. The device is now ready for the user to repeat the operation just described.

The drawings show embodiments which are intended to be thrown away after all the containers have been used. Alternatively, however, the device could comprise a replaceable cartridge having the stacks of unused and used containers therein, with the cartridge being replaced once all the containers had been used. The cartridge could include all or part of a slider mechanism for transferring containers from one stack to the other.

CLAIMS:

1. An inhalation device by means of which material in powder form can be inhaled, comprising means for holding a stack of unused powder containers, means for feeding each of the containers to a use station, and inhalation means for enabling the powder to be inhaled from a container at a use station.

2. A device according to claim 1, further comprising storage means for receiving each used container from the use station after the powder has been inhaled therefrom and collecting the containers therein.

3. A device according to claim 2, wherein the storage means comprises means for holding the used containers in the storage means so as to resist movement of the containers with respect thereto.

4. A device according to claim 3, wherein the storage means comprises means for holding a stack of used containers.

5. A device according to claim 4, wherein the said storage means comprises means for holding a plurality of stacks of used containers.

6. A device according to claim 5, wherein the said storage means is rotatable to enable each of the stacks successively to receive a used container from the use station.

7. A device according to claim 3, wherein the storage means comprises means defining a ramp along which used containers move as further used containers are stored.

8. A device according to any preceding claim, wherein the said holding means is adapted to hold a plurality of stacks of powder containers.

9. A device according to claim 8, wherein the said holding means is rotatable to bring each of the stacks successively into cooperation with the said feeding means.

10. A device according to any preceding claim, comprising means for resiliently urging the or each stack of unused containers in the holding means in a direction from a first end thereof towards a second end thereof, the said use station being at or operatively connected to the said second end.

11. A device according to any one of claims 4 to 6, comprising means for resiliently urging the or each stack of used containers in a direction from a first end thereof towards a second end thereof, the said use station being at or operatively connected to the said second end.

12. A device according to claim 1, comprising means for holding a first stack of unused powder containers, means for holding a second stack of used powder containers, means for feeding each of the containers from a first end of the first stack to a first end of the second stack, and a force-applying means, one end of the force-applying means applying a substantially constant force to a second end of the first stack and the other end of the force-applying means applying a substantially constant force to a second end of the second stack.

13. A device according to claim 12, wherein the said first and second stacks are situated along opposite arms of a U-shaped passage.

14. A device according to claim 12 or 13, wherein the said force-applying means comprises at least one resilient member.

15. A device according to any of one of claims 12 to 14, wherein the said feeding means comprises a linearly movable slider.

16. A device according to any one of claims 12 to 14, wherein the feeding means comprises a rotatably movable slider.

17. A device according to claim 15 or 16, wherein the inhalation means comprises an outlet spout having a cap which is movable from a closed position in which it covers the spout to an open position in which the spout is uncovered, and wherein the slider is operatively connected to the cap for movement thereby in response to movement of the cap.

18. A device according to claim 17, wherein the slider is connected to the cap by a lost motion connection which permits an initial amount of movement by the cap without corresponding movement of the slider.

19. A device according to any preceding claim, wherein the use station is located at one end of the stack of the unused containers.

20. A device according to any preceding claim, having a stack of unused powder containers held in the said holding means.

21. A device according to claim 20, wherein each of the powder containers has an opening therein, with adjacent containers being in contact with one another to close the

said openings at least except at one or both ends of the stack.

22. A device according to claim 21, wherein each container has an open-topped, powder-containing depression therein.

23. A device according to claim 22, wherein said inhalation means comprise wall means which cooperate with said depression to define a venturi.

24. A device according to claim 21, wherein each container is in the form of an annular ring defining a central powder-containing aperture.

25. A device according to any one of claims 21 to 24, wherein each said container opening is surrounded by a raised lip which is in sealing contact with the container adjacent thereto.

26. A device according to any preceding claim, comprising a safety catch which in an operative position prevents operation of the device and which in an inoperative position permits operation of the device.

27. A device according to claim 26, wherein the safety catch is biassed to the operative position.

28. An inhalation device by means of which material in powder form can be inhaled, comprising means for holding a stack of powder containers, means for resiliently urging the stack in a direction from a first end thereof to a second end thereof, a use station at or operatively connected to the said second end, and means for enabling powder to be inhaled from a container at the use station.

29. An inhalation device by means of which material in powder form can be inhaled, comprising means holding a stack of powder containers each of which has a powder-containing depression therein, means for feeding each of the containers to a use station, and inhalation means for enabling the powder to be inhaled from a container at a use station, said inhalation means comprising wall means which cooperate with the said depression to define a venturi.

30. An inhalation device by means of which material in powder form can be inhaled, comprising means for holding said material therein, means for actuating the device to permit inhalation, and a safety catch which in an operative position prevents actuation of the device and which in an inoperative position permits operation of the device.

31. A cartridge for use in an inhalation device, comprising means containing a first stack of unused powder containers, means for receiving at a first end used containers from a first end of the first stack, to form a second stack, and a force-applying means, one end of the force-applying means applying a substantially constant force to a second end of the first stack and the other end of the force-applying means applying a substantially constant force to a second end of the second stack.

32. A cartridge according to claim 31, further comprising means for feeding containers from said first end of said first stack to said first end of said second stack.

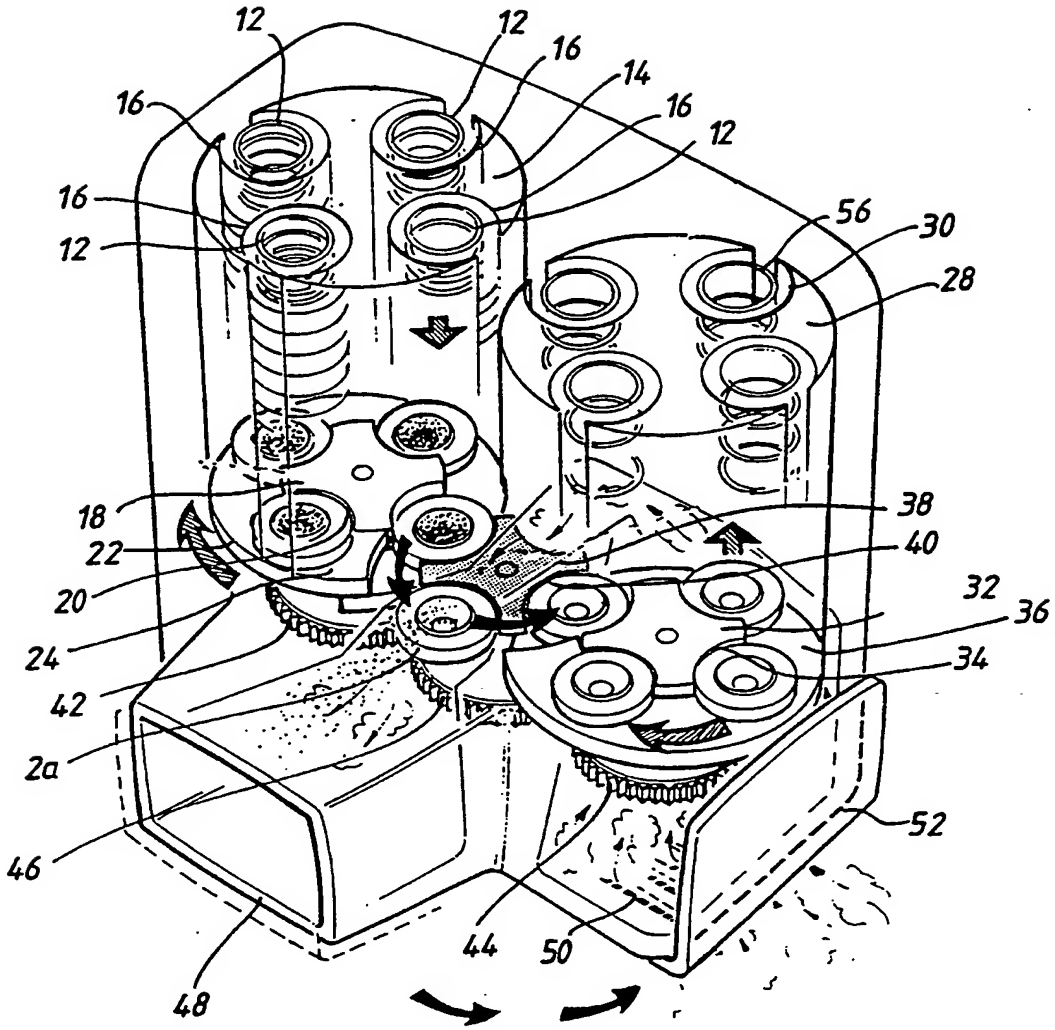
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Fig.1.

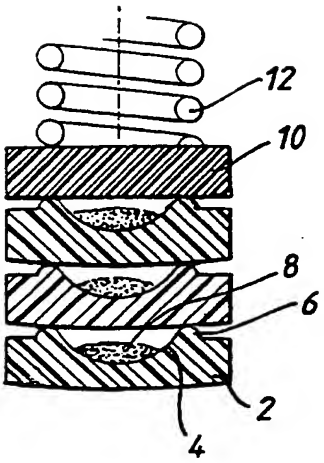

Fig.2a.

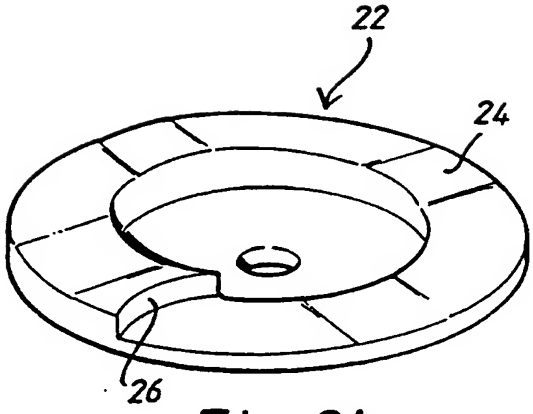

Fig.2b.

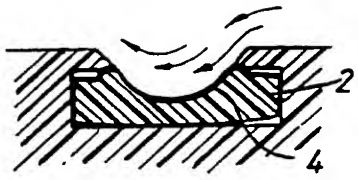

Fig.4a.

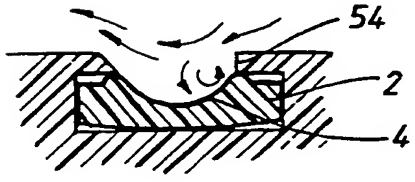

Fig.4b.

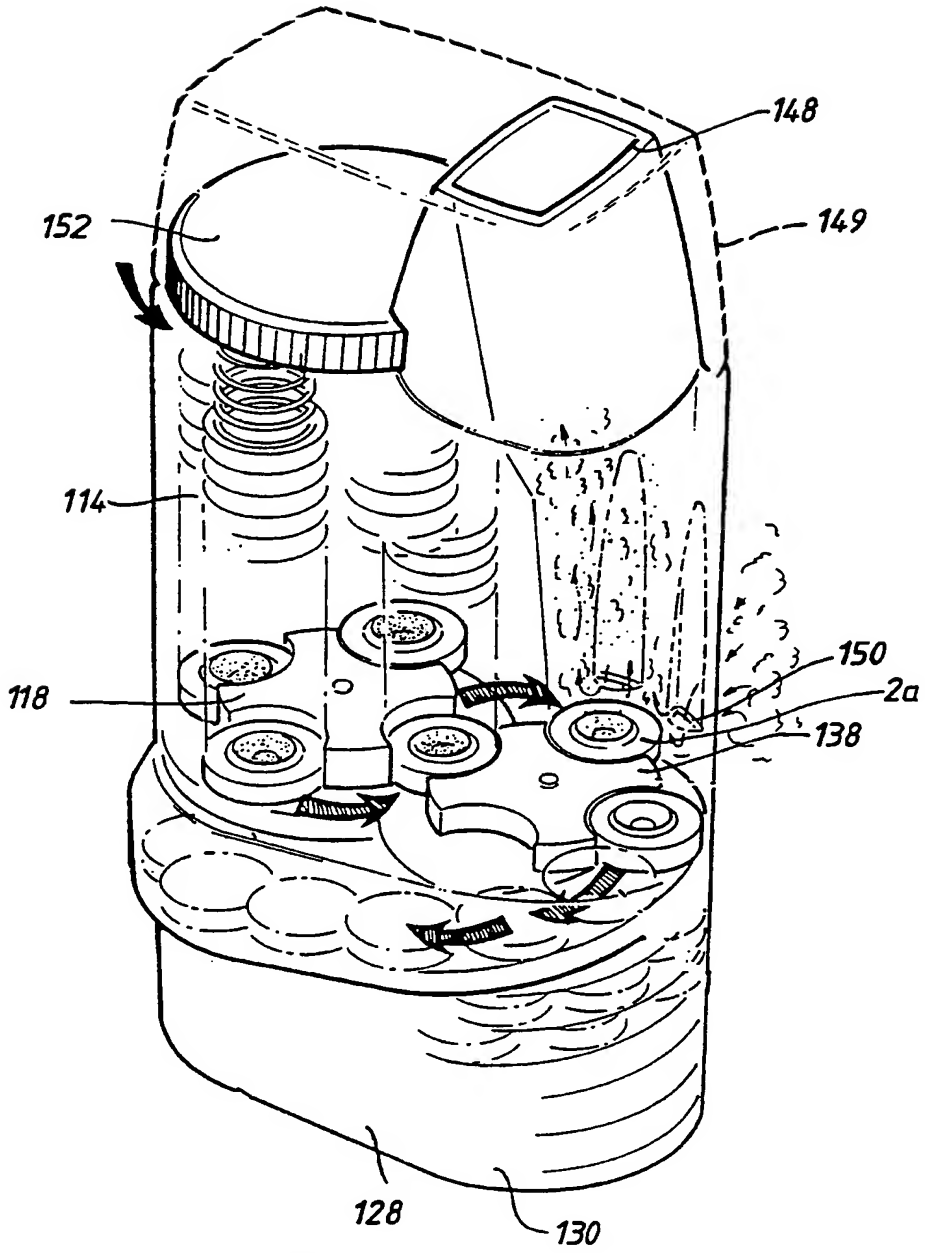

Fig.3.

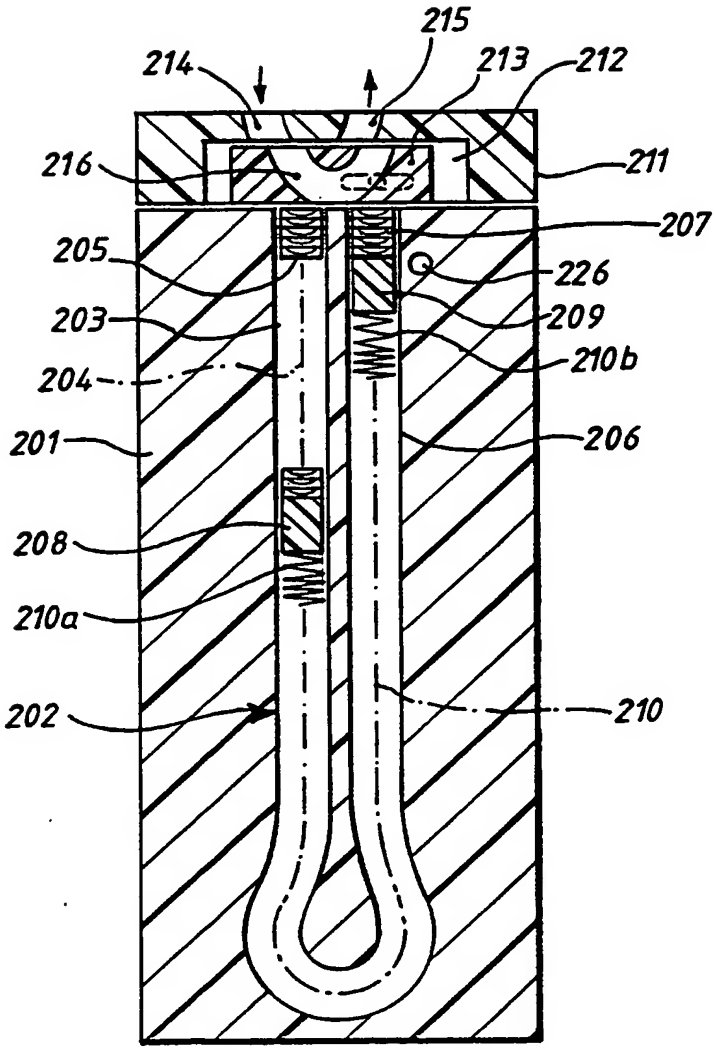
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Fig.5.

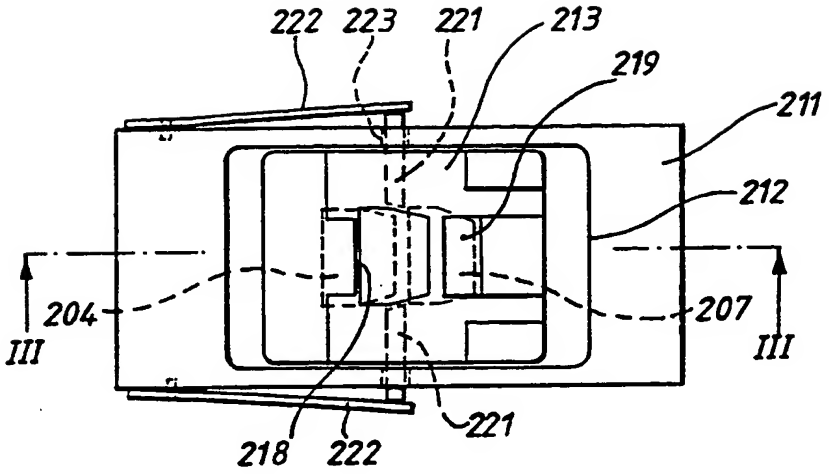
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Fig.6.

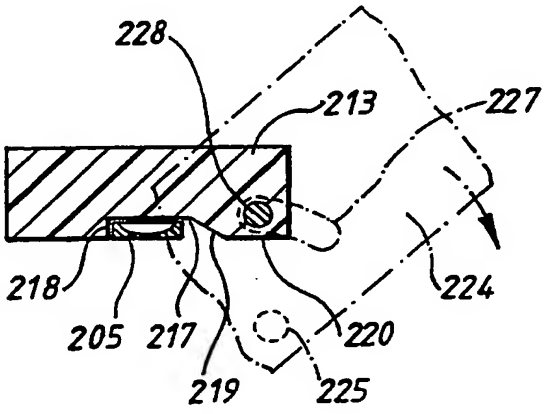
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Fig.7.

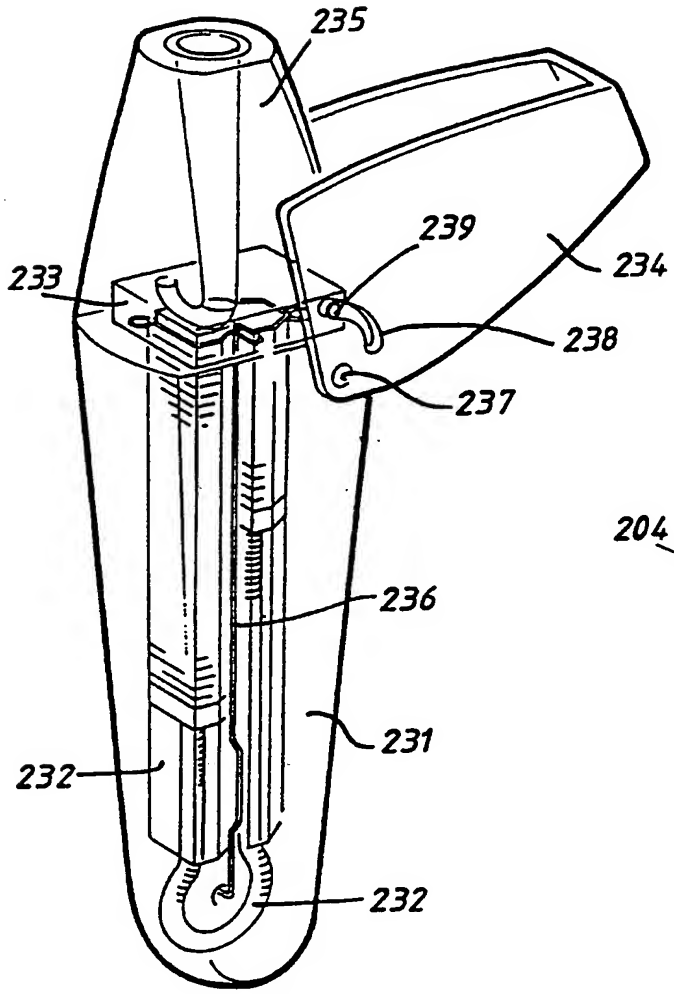

Fig.8

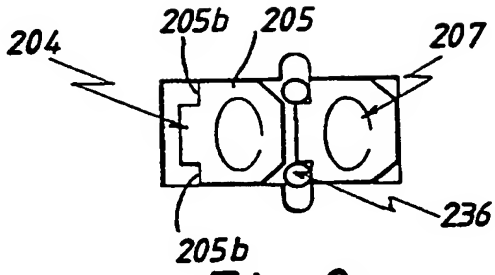

Fig.8a.

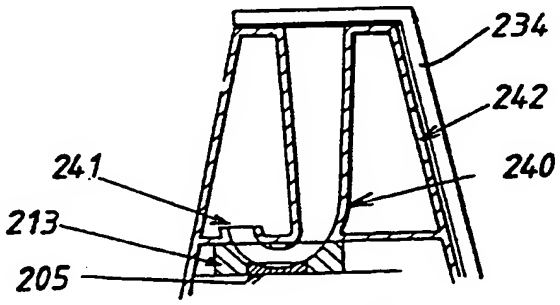

Fig.8b.

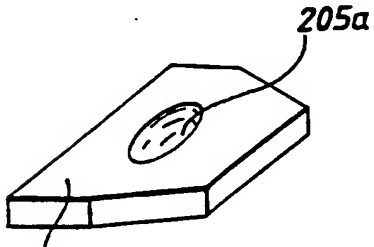

Fig.9.

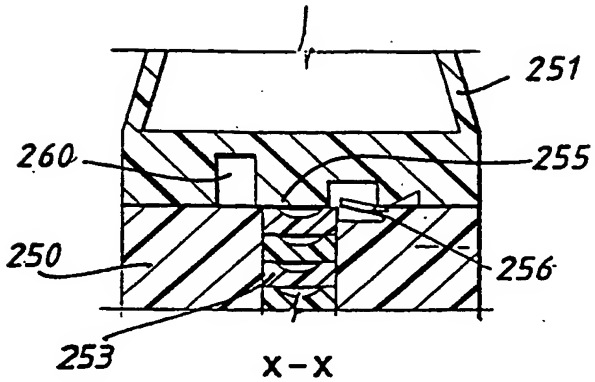

Fig.10a.

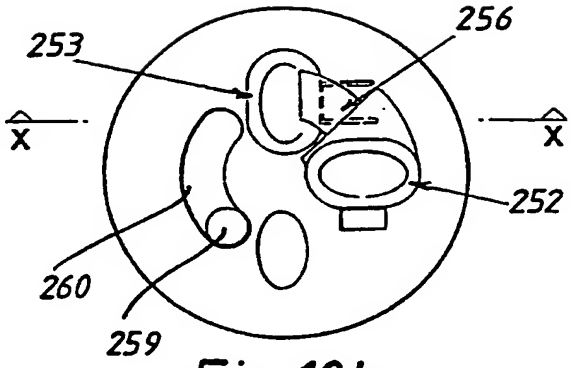

Fig.10b.

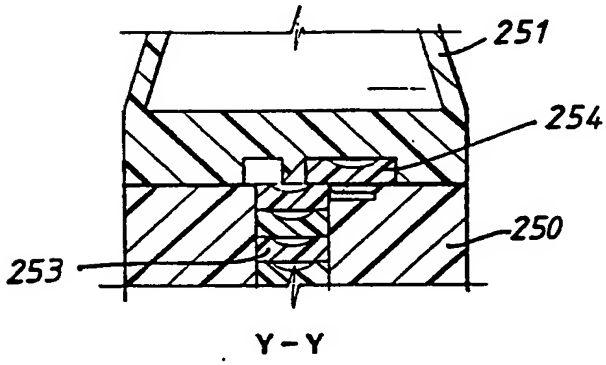

Fig.11a.

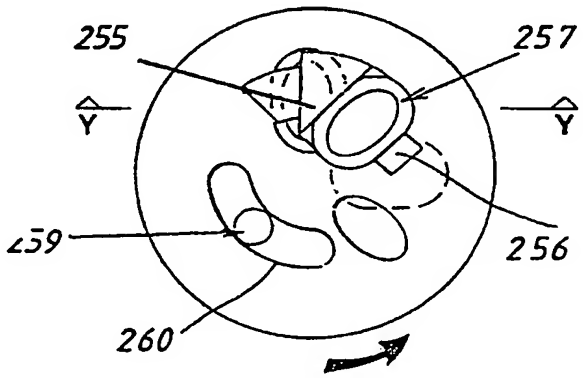

Fig.11b.

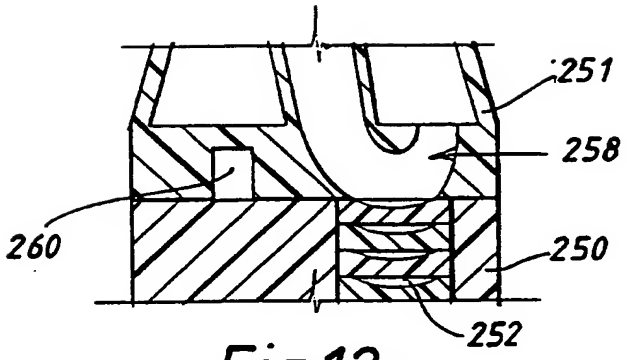

Fig.12a.

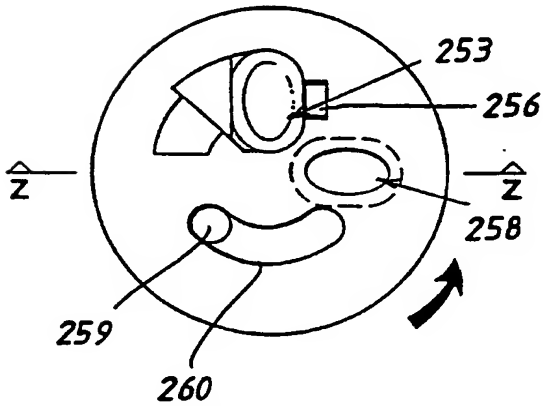

Fig.12b.

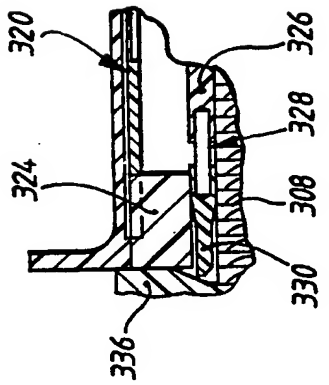

Fig.13a.

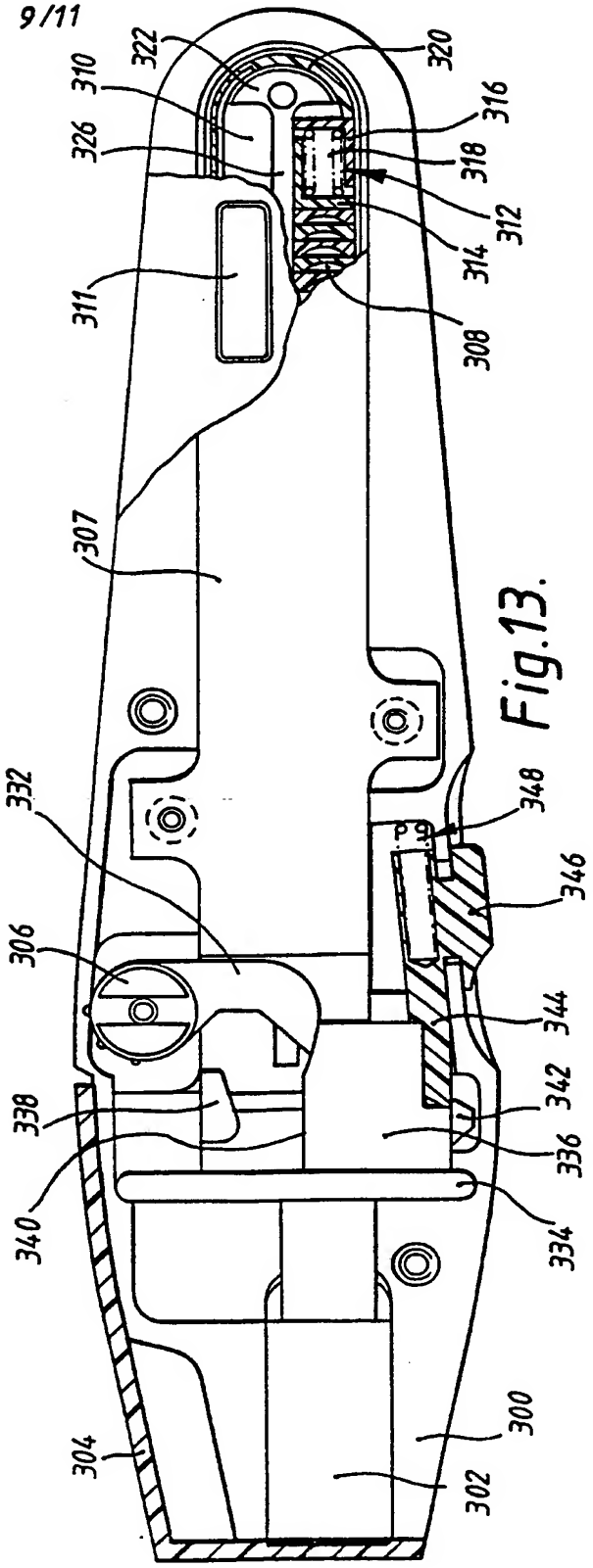

Fig.13.

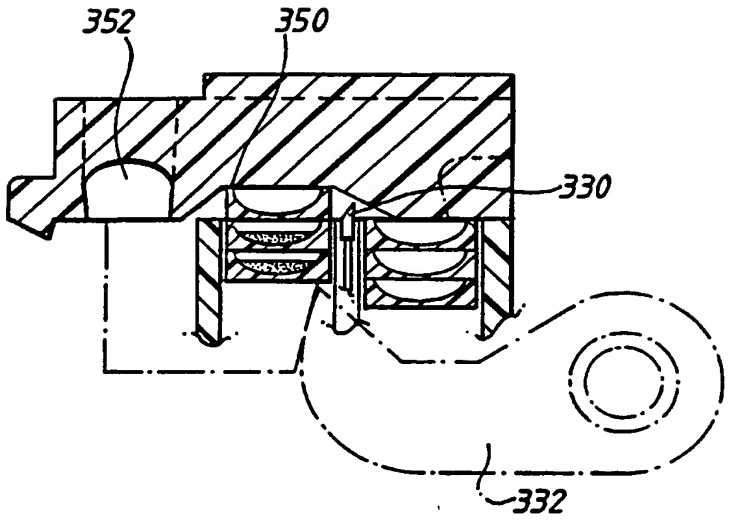

Fig.14a.

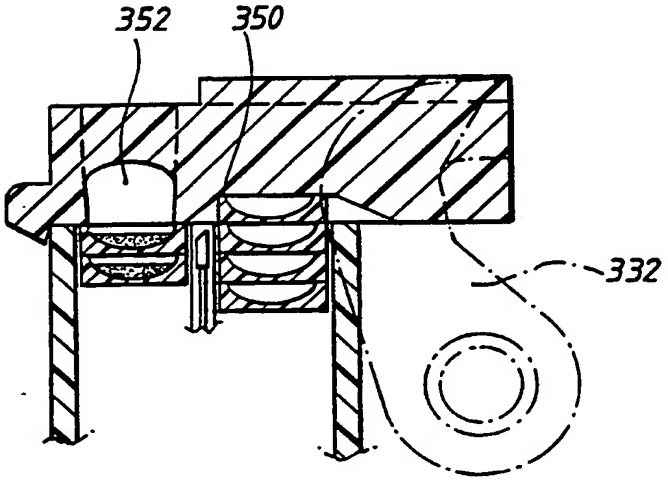

Fig.14b.

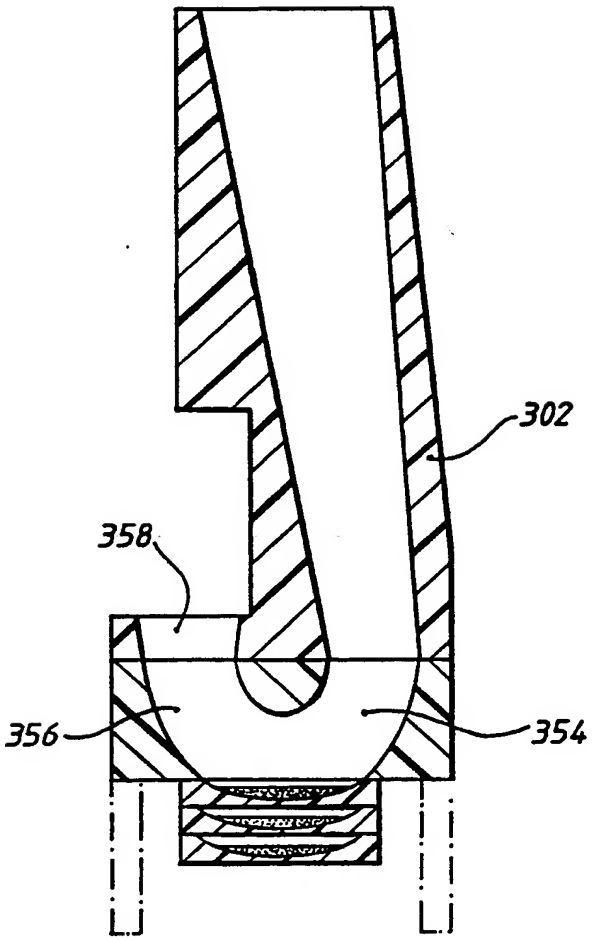

Fig.15.

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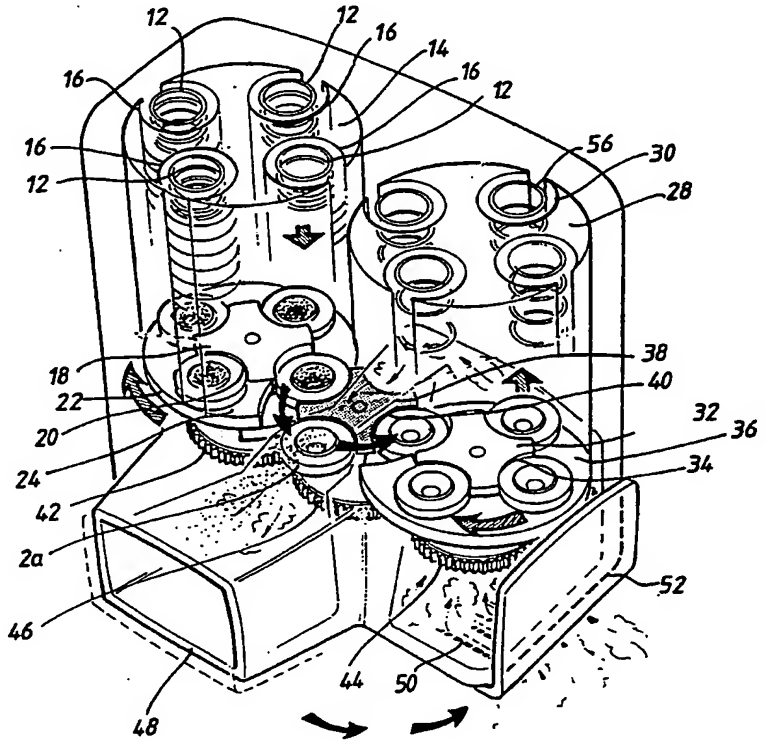
(54) Title: INHALATION DEVICE

(57) Abstract

An inhalation device is provided by means of which material in powder form can be inhaled. A stack of powder containers (2) is held in the device and is urged towards one end by a spring (12) or other resilient member. A use station is located at or adjacent that end, where powder can be inhaled from a container (2a) at the use station. Used containers (2) are fed to a storage area, for example a second stack which may be interconnected at its lower end, via the resilient member, with the lower end of the first stack.



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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/EP 93/01410

A. CLASSIFICATION OF SUBJECT MATTER

A 61 M 15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5 048 514 (L. RAMELLA) 17 September 1991 (17.09.91), the whole document; especially column 4, lines 6-8; column 5, lines 6-56; column 6, line 22 - column 7, line 28.	1,8,9, 20
Y		26
A		19,28, 29
	--	
Y	GB, A, 2 061 735 (RIKER LAB.) 20 May 1981 (20.05.81), fig. 5-7; page 6, lines 3-57.	26
A		1,29
	--	

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
06 April 1994	20. 04. 94

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A1, 90/13 328 (RIKER LAB.) 15 November 1990 (15.11.90), fig. 10; page 3, line 33 - page 4, line 5; page 24, lines 5-14; claims 1,3,11, 14,15,28.	1,28, 29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 93/01410

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

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because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims: 1-29;31,32 "Inhalation device...comprising means for holding a stack of...container, means for feeding the containers.../urging the stack...to a use station" and a "Cartridge for use in an inhalation device, comprising...first stack of...containers, means to form a second stack...".

Claim: 30 "Inhalation device...comprising...means for actuating..., and a safety catch, which prevents/permits operation of the device".

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-29;31,32

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANHANG — ANNEX — ANNEXE

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

to the International Search Report to the International Patent Application No.

au rapport de recherche international relatif á la demande de brevet international n°

PCT/EP 93/01410 SAE 74960

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The Office is in no way liable for these particulars which are given merely for the purpose of information.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche international visée ci-dessus. Les reseignements fournis sont donnés á titre indicatif et n'engagent pas la responsibilité de l'Office.

Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
US A 5048514		IT U0 8921132 IT U 216608	24-05-89 17-09-91
GB A1 2061735	20-05-81	AU A1 63960/80 AU B2 545574 CH A 656311 DE T 3050005 DK A 2865/81 EP A1 28162 EP B1 28162 FI A 811980 FI B 67026 FI C 67026 GB B2 2061735 IE B 50472 JP T2 57500862 NL A 8020393 NO A 812224 NO B 153595 NO C 153595 SE A 8104001 US A 4446862 WO A1 8101243 SE B 426290 SE C 426290	22-05-81 18-07-85 30-06-86 18-03-82 29-06-81 06-05-81 23-01-85 24-06-81 28-09-84 10-01-85 30-11-83 30-04-86 20-05-82 01-09-81 29-06-81 13-01-86 23-04-86 26-06-81 08-05-84 14-05-81 27-12-82 21-04-83
WO A1 9013328	15-11-90	AU A1 55395/90 AU A1 55588/90 AU B2 643435 AU B2 644790 CA AA 2058764 EP A1 470154 EP A1 472598 GB A0 8909891 GB A0 9000261 JP T2 4504671 JP T2 5501505 WO A1 9013327	29-11-90 29-11-90 18-11-93 23-12-93 29-10-90 12-02-92 04-03-92 14-06-89 07-03-90 20-08-92 25-03-93 15-11-90